

### **Remarks**

Upon entry of the present amendment, claims 13-37 are pending in the instant application. Claim 10 has been canceled without prejudice or disclaimer. Applicants hereby reserve the right to pursue canceled subject matter in subsequently filed continuing applications.

Claims 22 and 33 have been amended to clarify that the host cell of claims 22 and 33 are isolated. Support for the amendment can be found throughout the specification, for example, at page 149, paragraph 345 to page 161, paragraph 386.

The title has been amended to clearly indicate the invention to which the claims are directed. The specification has been amended to (a) reflect that Figure 1 contains three subparts (1A-1C); and (b) properly reference trademarks.

Accordingly, no new matter has been entered and entry of the present amendment is respectfully solicited.

#### **I. Objections to the Specification**

(a) The Examiner has objected to the title of the invention for allegedly not being descriptive. *See*, page 3, paragraph 3 In accordance with the Examiner's requirement, Applicants have amended the title to "Keratinocyte Growth Factor-2 Polynucleotides." Applicants respectfully request the Examiner to reconsider and withdraw this objection.

(b) The Examiner has also objected to the specification because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. *See*, page 3, paragraph 4. Applicants have amended the specification, to the best of their knowledge, to properly identify the trademarks used in the specification. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this objection.

#### **II. Non-Statutory Subject Matter Rejection Under 35 U.S.C. § 101**

The Examiner has rejected claims 22 and 33 under 35 U.S.C. § 101 for allegedly containing non-statutory subject matter. In particular, the Examiner alleges that the claimed host cells "do not sufficiently distinguish over cells that exist naturally." *See*, page 4, paragraphs 1-2. In accordance with the Examiner's suggestion, Applicants have amended

claims 22 and 33 to insert “isolated” before host cell, thereby obviating the Examiner’s rejection. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

### **III. Enablement Rejections Under 35 U.S.C. § 112, First Paragraph**

(a) The Examiner has rejected claims 13, 17-24, and 28-34 under 35 U.S.C. § 112, first paragraph for allegedly not fully meeting the deposit requirements. See, paragraph spanning pages 4-5.

In response, Applicants’ representative also hereby gives the following assurance by signature below:

Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit was made on December 16, 1994, accepted by the ATCC, and given ATCC Accession Number 75977. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 75977 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the ATCC Deposit Receipt for Accession Number 75977 is enclosed herewith as Exhibit A.

Applicants assert that the above statement obviates the Examiner’s concerns. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

(b) The Examiner has also rejected claims 22-23 and 33-34 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. In particular, the Examiner has alleged that the specification “does not reasonably provide enablement for a host cell comprising an expression vector”. See, page 5, paragraph 2. Moreover, the Examiner has interpreted the claims as “reading on isolated host cells, as well as host cells in the context of a multicellular, transgenic organism and host cells intended for gene therapy.” See, paragraph spanning pages 5-6.

Applicants respectfully disagree. However, in the interest of facilitating prosecution, and in no way in acquiescence to the Examiner's rejection, Applicants have amended claims 22 and 33 to reflect that the host cells are "isolated". Accordingly, Applicants assert that the present amendment obviates the Examiner's concerns and respectfully request the Examiner to reconsider and withdraw this rejection.

#### **IV. Double Patenting Rejections**

The Examiner has rejected claims 13-34 on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over various claims of U.S. Patent No. 6,077,692.

In response, Applicants have enclosed herewith a terminal disclaimer that disclaims the terminal part of the statutory term of any patent granted on the instant application that would extend beyond the expiration date of the full statutory term of any patent granted on U.S. Patent No. 6,077,692. The filing of the terminal disclaimers is not an admission that the claimed invention is unpatentable in view of the claimed subject matter in the reference U.S. patent. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.


### Conclusion

Entry of the above amendment is respectfully solicited. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: *October 20, 2006*

Respectfully submitted,

By   
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MJH/KC/pb

# EXHIBIT A



# American Type Culture Collection

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## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences, Inc.  
Attention: Craig A. Rosen, Ph.D.  
9620 Medical Center Drive, Suite 300  
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences, Inc.

Identification Reference by Depositor and ATCC Designations:

DNA Plasmids:

366885A ATCC 75977 PF 155 PCT. US

The deposits were accompanied by: \_\_\_\_ a scientific description \_\_\_\_ a proposed taxonomic description indicated above.

The deposits were received December 16, 1994 by this International Depository Authority and have been accepted.

#### AT YOUR REQUEST:

X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested January 5, 1995. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

  
Annette L. Bade, Director, ATCC Patent Depository

Date: January 5, 1995

cc: Greg Ferraro